510(k) Summary

SEP 2 3 2013

Applicant's Name and Address

Submitter: Cendres+Métaux SA
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Contact Person: Tanja Bongni
Regulatory Affairs Manager

Date of Submission: May 23, 2013

Name of the Device

Trade Name: SFI-Bar®
Common Name: Abutment, Dental, Endosseous implants
Classification Name: Endosseous Dental Implant Abutment
Regulation Number: 21 CFR 872.3630

Legally Marketed Device to which Equivalence is Claimed (Predicate Device)

Predicate Device(s): K083876, K111390, K071638, K042429, K073268, K053152, K073282

Description of the Device

Device Description: The SFI-Bar® provides the connection between compatible dental implant systems for the fixation of removable overdentures. The SFI-Bar® consists of an implant adapter (abutment) and a stress-free bar for the fixation of removable overdentures. The implant adapter is screwed into the dental implant.

The implant adapter (abutment) fit the Thommen SPI® Element Platform Ø 4.0 mm / the Neoss ProActive Implant Ø 3.5 / 4.0 / 4.5 / 5.0 / 5.5 mm and the Straumann dental implants / ITI Dental Implant System® Standard Ø 4.1 and Ø 4.8 mm / Standard Plus Ø 4.1 mm and Ø 4.8 mm / Tapered Effect Ø 4.1 and Ø 4.8 mm and Regular Neck (RN) Ø 4.8 mm and the BioHorizons Implant Systems Tapered Internal Implants / Internal Implants –.bone level / Single-stage Implants – tissue level (Implant Platform: Ø 3.5 mm, Ø 4.5 mm, Ø 5.7 mm).

Intended Use of the Device:

The SFI-Bar® is intended to be used with the implant manufacturer's (Table 1) implant to provide support for fixation of overdentures.

Table 1 Compatible Commercial Implant Manufacturers:

Implant Manufacturer	Implant System	Implant Platform Diameter:
Institut Straumann	ITI Dental Implant System®	Standard 4.1 and 4.8 mm / Standard Plus 4.1 and 4.8 mm / Tapered Effect 4.1 and 4.8 mm / Regular Neck (RN) 4.8 mm
Thommen Medical	SPI® Element Platform	4.0 mm
Neoss	Neoss ProActive Implant	3.5 / 4.0 / 4.5 / 5.0 / 5.5 mm
BioHorizons	Tapered Internal Implant – bone level	Ø 3.5 mm, Ø 4.5 mm, Ø 5.7 mm
	Internal Implants –bone level	
	Single-stage Implants – tissue level	

Summary Technological Characteristics:

The proposed implant adapters are substantially equivalent to the currently marketed predicate devices. The intended use, basic design, fundamental operating principles and manufacturing procedures are the same as the predicate devices.

The material of the implant adapters conform to ASTM F 136, Wrought Titanium-6Aluminium-4Vanadium ELI Alloy for Surgical Implant applications (UNS R 56401). The parts for the SFI-Bar® System are manufactured from wires.

Comparison /Compatibility Substantially Equivalence:

The proposed implant adapters are substantially equivalent to the currently marketed predicate devices. The intended use, basic design, fundamental operating principles and manufacturing procedures are the same as the predicate device.

To ensure compatibility the following process was carried out:
The implant adapters are developed and manufactured in close cooperation with the implant companies (see Table 1, column "Implant Company").
There are Quality Agreements between Cendres+Métaux and the implant companies in place. Those agreements handle among other things the Design Control, Change Control, Complaint Handling and Post Market Surveillance.

Table 2 summarizes the substantial equivalence comparison to the predicate device:

Table 2 Substantial Equivalence Comparison to Predicate Devices:

	SFI-Bar®	**Predicate Devices**		Comparison/ Performance "Predicate Devices"
510(k) No.	Candidate	K083876, K111390	K071638, K042429, K073268, K053152, K073282	---
Propriety Name	SFI-Bar®	SFI-Bar®	"BioHorizons Tapered Internal Implant System", "The Prodigy System™ Dental Implants", "BioHorizons Single-stage Implant", "BioHorizons Single-stage Implant Systems", "BioHorizons Internal Implant System"	---
Model no or System	05001022, 05001021, 05001020, 05001019, 05001023, 05001027, 05001026, 05001025, 05001024, 05001028, 05001032, 05001031, 05001030, 05001029, 05001033	05000576, 05000577, 05000578, 05000579	Tapered Internal Implants - bone level, Ø 3.8 (y) / 4.6 (g) / 5.8 (b). Internal Implants – bone level, Ø 3.5 (y) / 4.0 (g) / 5.0 (b) / 6.0 (b). Single- stage Implants – tissue level, Ø 3.5 (y) / 4.0 (y&g) / 5.0 (g&b) / 6.0 (b).	---
Common Name:	Abutment for Endosseous Implant (Dental)	Abutment for Endosseous Implant (Dental)	Endosseous dental implant	---
Manufacturer	Cendres+ Métaux SA	Cendres+ Métaux SA	BioHorizons Implant Systems, Inc.	---
Product Codes	NHA	NHA	DZE	Both SFI-Bar®s are within the same product

	SFI-Bar®	**Predicate Devices**		Comparison/ Performance "Predicate Devices"
510(k) No.	Candidate	K083876, K111390	K071638, K042429, K073268, K053152, K073282	---
				code. All predicate devices are within a dental application.
Regulation	872.3630	872.3630	872.3640	---
Indicated use	Intended to be used with the implant manufacturer's implant (Table 1) to provide support for fixation of overdentures.	Intended to be used with the implant manufacturer's implant (Table 1: SPI® Element Platform 4.0 mm implant) to provide support for fixation of overdentures.	Dental implant	⇨ Equivalent to SFI-Bar®
Manu-facturing Process	Machined. Surface treated (anodized).	Machined.	Machined. Surface treated (anodized).	All SFI-Bar® Implant adapter are machined. The new devices within this submission are also partially anodized. The anodization process has no influence on the safety & effectiveness of the device. Therefore, it can be stated that the manufacturing process is equivalent to the SFI-Bar® (predicate devices). ⇨ Equivalent to SFI-Bar® BioHorizons implants are also surface treated (same color coding).

	SFI-Bar®	Predicate Devices		Comparison/ Performance "Predicate Devices"
510(k) No.	Candidate	K083876, K111390	K071638, K042429, K073268, K053152, K073282	---
Operating Principle / Basic Design	Impression taking: Optional, preassembled (plug-in connection). Abutment implant connection: Screw fixation. Connecting principle to overdenture: Retentive system. Cleaning procedures for patient: Common procedure for oral hygiene. Patient handling: Common cleaning and insertion of prosthesis.	Impression taking: Optional, preassembled (plug-in connection). Abutment implant connection: Screw fixation. Connecting principle to overdenture: Retentive system. Cleaning procedures for patient: Common procedure for oral hygiene. Patient handling: Common cleaning and insertion of denture.	Not relevant	⇨ Equivalent to SFI-Bar®
Materials incorporated into key functional elements	Titanium	Titanium	Not relevant	⇨ Equivalent to SFI-Bar®
Shelf Life	95% after 10 years	95% after 10 years	Not known by Cendres+Métaux SA	⇨ Equivalent to SFI-Bar®
Packaging and sterilization	Dentalblister, non-sterile.	Dentalblister, non-sterile. Tubular bag, non-sterile	Not relevant	⇨ Equivalent to SFI-Bar®

Performance Data: Torque tests, application testing and functional testing have been conducted to evaluate the performance characteristics of the additional SFI-Bar®. The test methods used were the same as in the predicate device. Testing has shown that the SFI-Bar® is equivalent in performance characteristics to the predicate SFI-Bar®. The acceptance criteria were met.

Summary of Testing to Demonstrate Safety and Effectiveness / Conclusion:	Non-clinical test data was used to support the substantially equivalence claim. Clinical testing was not necessary. Non-clinical testing consisted of analysis of platforms to identify worst-case test samples. Fatigue testing was not done as the basic design is the same than the predicate device. The evaluation was based on FDA guidance "Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments." Torque tests, application and functional tests have been carried out. The summary of technological characteristics as well as the torque test, application and functional testing indicate that the device is safe and effective for its intended use and performs as well or better than the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

September 23, 2013

Cendres & Metaux SA
Ms. Tanja Bongni
Regulatory Affairs Manager
Rue De Boujean 122
2501 Biel/Bienne, Switzerland

Re: K131526
Trade/Device Name: SFI-Bar®
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA
Dated: September 11, 2013
Received: September 13, 2013

Dear Ms. Bongni:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Richard C.
Chapman
2013.09.23
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for

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131526

Device Name: SFI-Bar®

Indications for Use:

The SFI-Bar® is intended to be used with the implant manufacturer's implant (Table 1) to provide support for fixation of overdentures.

Only the implant systems listed in Table 1 may be used with SFI-Bar®.

The compatible implant systems are specified in Table 1 below

Implant Manufacturer	Implant System	Implant Platform Diameter
Institut Straumann	ITI Dental Implant System®	Standard 4.1 and 4.8 mm / Standard Plus 4.1 and 4.8 mm / Tapered Effect 4.1 and 4.8 mm / Regular Neck (RN) 4.8 mm
Thommen Medical	SPI® Element Platform	4.0 mm
Neoss	Neoss ProActive Implant	3.5 / 4.0 / 4.5 / 5.0 / 5.5 mm
BioHorizons	Tapered Internal Implant – bone level	Ø 3.5 mm, Ø 4.5 mm, Ø 5.7 mm
	Internal Implants –bone level	
	Single-stage Implants – tissue level	

Table 1 Compatible Implant Systems

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND / OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Andrew I. Steen -S
2013.09.23 08:00:13 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

Page 1 of 1

510(k) Number: K131526